HID 613

NDA 50-316/S-006
NDA 50-317/S-012

OCT 2 8 1998

Pharmacia & Upjohn
Attention: Rebecca K. Tong, M.S.
Regulatory Manager, U.S. Regulatory Affairs
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Ms. Tong:

Please refer to your supplemental new drug applications dated June 29, 1989, received July 6, 1989, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lincocin® (lincomycin hydrochloride) Capsules and Lincocin® (lincomycin hydrochloride) Sterile Solution. We note that these applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated November 16, 1990, June 6, 1991, October 25, 1993, August 26,1996, January 29,1997, June 29, 1998. Your submission of August 26, 1996 constituted a full response to our February 5, 1996 action letter.

These supplemental new drug applications provide for the following changes to the labeling:

1. Revisions to the box **WARNING** and **WARNINGS** sections, particularly statements regarding *pseudomembranous colitis*.
2. Revisions to the **DESCRIPTION** section to include the chemical name, molecular formula, molecular weight, and structural formula of lincomycin hydrochloride.
3. Revisions to the **CLINICAL PHARMACOLOGY** section, including lists of microorganisms in the ***Microbiology*** subsection.
4. Addition of the statements “Bacteriologic studies should not be performed to determine the causative organisms and their susceptibility to lincomycm“, “Indicated surgical procedures should be performed in conjunction with antibiotic therapy”, and “Lincomycin is not indicated in the treatment of minor bacterial infections or viral infections” to the **INDICATIONS AND USAGE** section.
5. Numerous revisions to all subsections of the **PRECAUTIONS** section, including a new ***Carcinogenesis, Mutagenesis, Impairment of Fertility*** subsection.
6. Revisions to the **ADVERSE REACTIONS** section, including the ***Gastrointestinal, Hematopoietic, and Hypersensitivity Reactions*** subsection.
7. Addition of an **OVERDOSAGE** section.
8. Deletion of the illustrations under “Suggested Administration Techniques”.
9. Numerous editorial revisions throughout.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the enclosed labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted draft labeling (package insert dated June 29, 1998). Marketing the products with FPL that is not identical to the approved labeling text may render the products misbranded and unapproved new drugs.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavy-weight paper or similar material.For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 50-316/S-006,50-317/S-012." Approval of these submissions by FDA is not required before the labeling is used.

In addition, please submit a new and separate supplement that updates the ***Microbiology*** subsection of the **CLINICAL PHARMACOLOGY** section of the label in accordance with the Agency's letter to All NDA Holders dated January 26,1993, and the attached updated memo.

If additional information relating to the safety or effectiveness of this drug becomes available before we receive the final printed labeling, revision of that labeling may be required.

If a letter communicating important information about this drug product (i.e., a "Dear Healthcare Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Beth Duvall-Miller, Project Manager, at (301) 827-2125.

Sincerely yours,

Gary K. Chikami, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure